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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,081	10/03/2003	Hans-Michael Dosch	2560.001	3553

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,081	DOSCH ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 5-7* is/are pending in the application.

4a) Of the above claim(s) *1,3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Seq. Comparison*.

DETAILED ACTION

Applicant's response filed on 9/12/2005 is acknowledged. Claims 1-7 are pending. Claims 1,3 and 4 were withdrawn, claims 2 and 5were amended and new claims 6 and 7 were added. Claims 2 and 5-7 are under consideration. The sections of 35 U.S.C. not included in this office action can be found in a previous office action. An action on the merits follows.

Drawings

The objection to the drawings under 37 CFR 1.83(a) because they fail to show the histological details and banding patterns as described in the specification, is withdrawn in view of applicant's amendments to the drawings and the specification.

Claim Rejections - 35 USC § 112

The rejection of claims 2 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of applicant's amendments to the claims.

The rejection of claims 2 and 5 under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement is withdrawn in view of applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 2 and 5 under 35 U.S.C. 103(a) as being unpatentable over Karges et al. {Karges et al. (1997) Diabetes 46 :1548-1556}, further in view of Humphreys-Behr { Humphreys-Behr (1996) Adv. Dent. Res. 10:73-75}, is maintained.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karges et al. {Karges et al. (1997) Diabetes 46 :1548-1556}, further in view of Humphreys-Behr { Humphreys-Behr (1996) Adv. Dent. Res. 10:73-75}, and US Patent NO: 6,207,389 (3.27.2001), hereafter known as Dosch. This rejection was necessitated by amendment.

Karges et al. provides guidance on treatment of NOD mice with the ABBOS mimicry high-affinity peptide, in order to induce T-cell tolerance to ICA69 (Abstract). Further Karges et al. teaches that administration of the ABBOS mimicry peptide reduced diabetes incidence in NOD mice (pg. 1554, col.1, pgph 1554) and was able to induce cross-tolerance to the Tep69 epitope of ICA69 autoantigen (pg. 1551, Fig. 3). Karges does not treat these NOD diabetic mice have pSS.

Humphreys-Behr supplements the guidance of Karges et al. by teaching that the diabetic NOD mouse model also undergoes a corresponding loss in exocrine gland function related to lymphocyte infiltrates symptomatic of the pathophysiology of primary Sjögren's Syndrome.

Dosch supplements the guidance of Karges et al. by teaching an ABBOS sequence identical, SEQ ID NO:11, to the instantly claimed SEQ ID NO:2 (Co. 26, Table 1; see attached sequence comparison). Dosch teaches methods for preventing the development of T cell

mediated autoimmune diseases such as type I diabetes, in which susceptible subjects are treated with an antigen to prevent the expansion of sensitized T cells (Abstract).

Based on the guidance provided by Karges et al. on a method of treating an diabetes in NOD mice with the ABBOS mimicry high-affinity peptide by inducing tolerance of the mouse's ICA69 specific T-cells to ICA69, the guidance of Humphreys-Behr that some diabetic NOD mice develop pSS, and the guidance of Dosch on specific ABBOS antigens useful for preventing the development of T cell mediated autoimmune diseases such as type I diabetes, it would be *prima facie* obvious to the person of ordinary skill in the art at the time the invention that treatment of diabetic NOD mice with the ABBOS mimicry high-affinity peptide that induced tolerance in ICA69 specific T cells to ICA69 would also treat any other disease caused by the activity of ICA69 specific T cells, such as pSS in the same mouse.

A practitioner in the art would be motivated to treat NOD mice with diabetes and pSS with an ABBOS peptide, such as SEQ ID NO:11 in order to induce tolerance of the mouse's ICA69 specific T-cells to ICA69 and thus to treat the diabetes, which would also treat any other ICA69 T-cell mediated autoimmune disease, such as pSS .

The person of ordinary skill in the art would have a reasonable expectation of success because the method of Karges et al. treats diabetes in the mouse by inducing tolerance in ICA69 specific T cells and therefore any other diseases caused by these ICA69 specific T cells would also be treated by the induction of tolerance.

Response to Arguments

Applicant's arguments filed 9/12/2005 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion or motivation in the cited references to treat Sjögren's Syndrome. It appears that Applicant is arguing that the cited references do not expressly suggest the claimed invention. However, it is well established in case law that a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests. In re Burkel, 201 USPQ 67 (CCPA 1979). Furthermore, in the determination of obviousness, the state of the art as well as the level of skill of those in the art are important factors to be considered. The teaching of the cited references must be viewed in light of these factors.

Further, applicant correctly identified the examiner's main point when they stated that: "the examiner believes that treatment of diabetic NOD mice with the ABBOS peptide will also treat any other disease caused by the activity of ICA69 specific T Cells, in particular, primary Sjögren's Syndrome in the same treated NOD mice." Applicant argues that the mice used to determine that the ABBOS peptide was useful in treating Sjögren's Syndrome were specially bred NOD mice that do not develop diabetes and insulitis. Further they argue that prior to the instant invention the ICA69 was not known to be involved in Sjögren's Syndrome. Finally, they argue that one of ordinary skill in the art would not have expected that since the induction of tolerance to ICA69 with ABBOS was successful in treatment of diabetes in NOD mice it would also be successful in treatment of primary Sjögren's Syndrome.

Applicant's invention demonstrates that by inducing tolerance to ICA69 by treatment with ABBOS the symptom's of primary Sjögren's Syndrome can be treated. As previously stated: Karges et al. provides guidance on treatment of NOD mice with the ABBOS mimicry

high-affinity peptide, in order to induce T-cell tolerance to ICA69 (Abstract). Further Karges et al. teaches that administration of the ABBOS mimicry peptide reduced diabetes incidence in NOD mice (pg. 1554, col.1, pgph 1554) and was able to induce cross-tolerance to the Tep69 epitope of ICA69 autoantigen (pg. 1551, Fig. 3). Humphreys-Behr teaches that NOD mice undergo a corresponding loss in exocrine gland function related to lymphocyte infiltrates symptomatic of the pathophysiology of primary Sjögren's Syndrome. Therefore by treating the diabetic mice with the ABBOS peptide Karges obviously has treated their symptoms of primary Sjögren's Syndrome. Since both primary Sjögren's Syndrome and diabetes occurs in these NOD mice and they are both mediated by ICA69 specific T-cells. The induction of tolerance in these T-cells to treat diabetes must also treat primary Sjögren's Syndrome. The issue is not the lack of knowledge of the skilled practitioner in the art, the issue is whether the invention claimed was obvious to practice from the prior art.

Applicant's claimed invention is akin to claiming a method of using aspirin to reduce the risk of blood clots. Since people have being taking aspirin for pain for over 100 years for headaches they are at the same time reducing their incidence of blood clots. The methods cannot be separated since they both are dependent only on an inherent property of the aspirin. Similarly the method of treating primary Sjögren's Syndrome is dependent on treating a mammal with ABBOS. When the ABBOS is used to treat the NOD mice of Karges, it obviously also treats any other diseases mediated by ICA69 T-cells in these NOD mice, such as primary Sjögren's Syndrome. No hindsight is required. Further, it is noted, however, that "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at

the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin, 443 F2d. 1392, 170 USPQ 209, 212 (CCPA 1971). For the reasons of record stated, above and in the previous action of 9/12/2005, the rejection over this issue is maintained.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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